(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 January 2002 (10.01.2002)

PCT

(10) International Publication Number
WO 02/02037 A1

(51) International Patent Classification[7]: A61F 5/00

(21) International Application Number: PCT/US01/21178

(22) International Filing Date: 2 July 2001 (02.07.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/608,663 30 June 2000 (30.06.2000) US

(71) Applicant: **DJ ORTHOPEDICS, LLC** [US/US]; 2985 Scott Street, Vista, CA 92083 (US).

(72) Inventor: **ENZERINK, Robert-Jan**; 2703 Emerald Bay Drive, Davis, CA 95616 (US).

(74) Agent: **NATAUPSKY, Steven, J.**; Knobbe, Martens, Olson & Bear, LLP, 16th Floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).

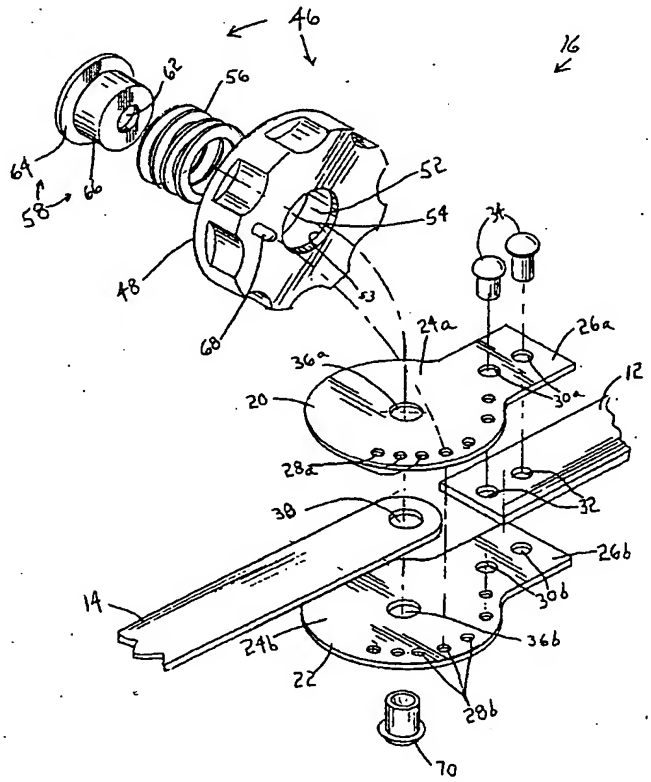
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

[Continued on next page]

(54) Title: ORTHOPAEDIC BRACE HAVING AN AXIALLY SETTABLE RANGE OF MOTION HINGE



(57) Abstract: An orthopaedic brace includes an upper strut (12) pivotally connected with a lower strut (14) by a range of motion hinge. The range of motion hinge is axially actuable to adjust/set the angular knob (46) of the hinge assembly is positionable into a plurality of settings corresponding to various ranges of motion for the hinge. The stop pin/adjustment knob (68/46) is axially and rotatably movable to set a range of flexion and/or extension motion.

WO 02/02037 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ORTHOPAEDIC BRACE HAVING AN AXIALLY SETTABLE RANGE OF MOTION HINGE

This application claims the benefit of U.S. Provisional Application Serial No. 60/156,241 which was filed on September 27, 1999.

Field of the Invention

The present invention relates to orthopaedic braces and, more particularly, to a range of motion hinge adaptable to orthopaedic braces used in stabilizing a joint after injury or invasive surgery.

Description of the Prior Art

In order to ensure the proper healing of a human joint after an injury or invasive surgery, it is often desirable to limit the pivotal motion of the human joint to a predetermined angular range between full extension and full flexion. The pivotal motion may be limited by a range of motion hinge disposed between an upper strut and a lower strut. The following U.S. Patents, which describe orthopaedic braces of this general type, are herein incorporated by reference to establish the nature of such range of motion braces, and how and why such equipment is used. U.S. Patent No. 4,531,515 issued to Rolfes on July 30, 1985 entitled "Exterior Orthopedic Adjustable Hinge Brace"; U.S. Patent No. 4,817,588 issued to Bledsoe on April 4, 1989 entitled "Motion Restraining Knee Brace"; U.S. Patent No. 5,052,379 issued to Airy et al., on October 1, 1991 entitled

"Combination Brace and Wearable Exercise Apparatus for Body Joints"; U.S. Patent No. 5,292,303 issued to Bastyr et al., on March 8, 1994 entitled "Hinged Orthopedic Brace Having An Adjustable Pivot Range"; U.S. Patent No. 5,409,449 issued to Nebolon on April 25, 1995 entitled "Detent Mechanism for a Hinged Orthopedic Brace"; and U.S. Patent No. 5,817,040 issued to Hess et al., on October 6, 1998 entitled "Knee and Elbow Orthosis".

It is well known that the range of motion braces described in the aforementioned incorporated patents suffer various problems, shortcomings and disadvantages. Most notably, the range of motion hinges tend to be difficult to operate, manipulate and adjust; to be bulky; to have high profiles that tend to snag on furniture, clothes and the like; to have complicated and hard to read adjustment mechanisms; and to have loose parts.

It is thus an object of the present invention to provide an orthopaedic brace that is easy to operate.

It is thus another object of the present invention to provide an orthopaedic brace that is easy to manipulate and/or adjust.

Summary of the Present Invention

The present invention provides a range of motion hinge for an orthopaedic brace that includes an axially actuated range of motion setting assembly.

In one form, the present invention is an orthopaedic joint brace that includes a first strut, a second strut, and a hinge assembly pivotally coupling the

first strut with the second strut and defining an axis of rotation. A range of motion of the hinge assembly is selectively settable by an axially actuated stop.

In another form, the present invention is an orthopaedic brace that includes an upper strut, a lower strut, and a hinge assembly disposed between the upper and lower struts. The hinge assembly provides for motion or movement of one of the struts about an axis corresponding to a joint axis. The hinge assembly is settable into a plurality of positions corresponding to a plurality of ranges of motion of the struts about the axis. The hinge assembly includes an axially actuated and rotatably mounted adjuster operable to selectively set the range of motion of the hinge assembly.

In yet another form, the present invention is an orthopaedic brace that includes an upper strut, a lower strut, a hinge assembly disposed between the struts and providing for movement of one of the struts about an axis corresponding to a joint axis, and an adjustment knob carried on the hinge assembly. The hinge assembly includes opposing plates, each opposing plate containing a pivot aperture and a plurality of circumferential apertures forming pairs of retaining apertures. Each pair of retaining apertures corresponds to a range of motion of the struts about the axis. The opposing plates are rigidly connected to one of the upper and lower struts and pivotally retaining the other strut therebetween. The adjustment knob includes a retaining pin for engagement in a selective one of pairs of retaining apertures to select a range of motion of the struts about the axis.

Accordingly, the present invention improves upon the prior art by providing a low-profile, range of motion hinge that is easily adjustable by the wearer. More specifically, the improved range of motion hinge may be adjusted without the use of tools, and it is smaller in diameter, is lighter in weight, and is lower in profile in comparison to the prior art. This cost-effective range of motion hinge allows the selective restriction of range of motion in both extension and flexion through axially actuated stops in an enclosed system of locking pins and stop apertures.

Brief Description of the Drawings

The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a side perspective view of an adjustable, motion-restraining knee brace containing an improved range of motion hinge assembly that embodies principles of the present invention showing the brace operatively connected to a human leg;

FIG. 2 is a side elevational view depicting the range of motion hinge of FIG. 1 showing an arbitrary degree of flexion and, in phantom, a full degree of extension;

FIG. 3 is an exploded, perspective view of the range of motion hinge assembly of FIG. 2; and

FIGS. 4A and 4B are cross-sectional views through the range of motion hinge assembly taken along line 4-4.

Corresponding reference characters indicate corresponding parts throughout the several views.

Detailed Description of the Invention

An orthopaedic brace 10 is shown in Fig. 1. Orthopaedic brace 10 is adapted to fit on a human limb in order to limit the range of motion of a human joint. While it is expected that this improved orthopaedic brace is adaptable to any of the joints of the human body, such as an elbow, an ankle or a hip, it will be described herein as used to aid the healing of the knee joint. Consequently, Fig. 1 shows the orthopaedic brace operatively connected to a human leg 18 through conventional means. Orthopaedic brace 10 includes an upper strut 12, a lower strut 14, and an improved range of motion hinge assembly 16 disposed between the upper strut 12 and the lower strut 14 while not shown, the orthopaedic brace preferably includes a like hinge and strut assembly on the opposite side thereof (of the leg) which cannot be seen in the figure.

Referring to Fig. 2, the improved range of motion hinge assembly 16 is shown in an arbitrary degree of flexion and, in phantom, in a full degree of extension with respect to the upper strut 12 and the lower strut 14. Also, shown is a release-and-adjustment knob assembly 46. The knob or adjustment assembly 46, has at least one movable bezel 48 with an easily readable, graded degree index scale 50. The bezel 48 is particularly rotatably movable about a center or hinge pivot pin 70. The graded degree scale 50 shows the arcuate

range of motion of the struts 12 and 14 relative to one another or the amount of rotatable movement allowed by the hinge assembly 16. Although not shown, the knob assembly 46 may, as will be described subsequently, also be adapted to include at least a second movable bezel that operates independently of the first bezel 48. The depicted degree index scale 50 shows, as an example, an included angle of 60 degrees at 15 degree intervals. It will be appreciated that the incremental angles and the maximum angles of extension and flexion may vary.

Fig. 3 further details the knob assembly 46. The bezel 48 defines at its center a cylindrical chamber 52 adapted to receive a spring retainer member 58. At the center of the chamber 52 is circular opening 54, of smaller radius than the chamber 52, formed the rest of the way through the bezel 48 and the bottom of the chamber 52. The spring retainer member 58 has a flanged-lipped top portion 64 and a cylindrical, elongated body portion 66. A circular opening 62 runs through the center of the spring retainer member 58. The spring retainer member 58 is adapted to receive about its body portion 66 a spring or like component 56, which slides onto or around the body portion 66 and is retained between the flange portion 64 and the bottom 53 of the chamber 52. The bezel 48 is fitted with a stop pin 68. Although not depicted, additional stop pins could also be attached to the bezel 48.

Fig. 3 also details further portions of the hinge assembly 16, that pivotally interconnects the upper strut 12 and the lower strut 14. The hinge assembly 16 includes a pair of outer and inner opposing base plates 20 and 22, which may be

identically configured. Each of the opposing base plates 20 and 22 has a generally circular body portion 24a and 24b respectively from which a generally rectangular connecting tab portion 26a and 26b respectively tangentially extends. Formed through the periphery of the body portions 24a and 24b are an aligned plurality of circumferentially spaced stop apertures 28a and 28 respectively. The apertures 28a and 28b are adapted to receive the stop pin 68. Also formed through the body portions 24a and 24b, at their centers, is a circular opening 36a and 36b respectively, adapted to receive the hinge pivot rivet 70, the function of which subsequently will be described.

A central end portion of the upper strut 12 is sandwiched and retained between the opposing base plates 20 and 22, as shown in Fig. 3, and anchored to the respective connecting tabs 26a and 26b of the opposing base plates 20 and 22 by means of two rivets 34. The two rivets 34 are extended down into aligned openings 30a and 30b formed through the respective tabs 26a and 26b, and through the aligned openings 32 in the upper strut 12. The central end portion of the lower strut 14 is also sandwiched and retained, pivotally, between the opposing base plates 20 and 22. The central end portion of the strut 14 has formed therethrough a circular opening 38, which is aligned with the central circular openings 36a and 36b respectively formed through the circular body portions 24a and 24b of the respective base plates 20 and 22. The hinge pivot rivet 70 pivotally connects the components of the hinge assembly 16 and the accompanying adjustment assembly 46 by extending down sequentially through the bezel chamber opening 54, the retainer opening 62, the outer plate 20 body

opening 36a, the lower strut opening 38, and the inner plate 22 body opening 36b.

Referring to Figs. 4A and 4B, the operation of the axially actuated hinge assembly 16 can be seen. In the steady-state, engaged configuration, the spring 56, exerts opposing pressure against the retaining lip 64 and the bottom 53 of the chamber 52, thereby biasing the adjustment knob assembly 46 axially downward towards the base plates 20 and 22. This downward bias urges the stop pin 68 to captively engage one of the selected plurality of pairs of stop apertures 28a and 28b. When the lower strut 14 is pivoted toward the upper strut 12, the lower strut 14 abuts against the stop pin 68, which in the engaged configuration extends all the way down through the opposing base plates 20 and 22 to create a positive stop. This configuration could limit either the angle of extension or of flexion.

Referring to Fig. 4B, a hand 72 disengages the stop pin 68 by pulling the bezel 48 against the spring 56 axially away from the opposing base plates 20 and 22. By maintaining the upward force against the compressed spring 56, the bezel 48 may be rotated to select any of the plurality of pairs of circumferentially spaced stop apertures 28a and 28b (or positions) that correspond to the desired angle limit as clearly depicted on the index scale 50.

Through the use of an undepicted, and unconnected stop pin, angle limits on both extension and flexion can be set simultaneously. The undepicted stop pin could be manually inserted from the back of the inner base plate 22 to limit the movement in whatever direction, extension or flexion, that the adjustment

assembly 46 described above is not limiting. Alternatively, in another undepicted embodiment, the adjustment assembly 46 can be adapted with an inner and an outer bezel. One of the two bezels could be adapted to control one stop pin as just described to limit, for example, the angle of extension. The other bezel could be adapted to work in opposition to the first bezel to limit the angle of movement in the other direction, for example flexion. This would be accomplished by reversing the direction of engagement and disengagement of the stop pin associated with the second bezel. Therefore, pushing down on the second bezel would disengage a stop pin from the back of the inner base plate 22, and releasing the second bezel would engage the stop pin.

Although the invention has been described in detail with reference to certain preferred embodiments, variations and modifications exist within the scope and spirit of the invention. Additional features of the invention will become apparent to those skilled in the art upon consideration of the detailed description of preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived.

Claims

What is claimed is:

1. An orthopaedic joint brace comprising:

a first strut;

a second strut; and

a hinge assembly pivotally coupling said first strut with said second strut and defining an axis of rotation, a range of motion of said hinge assembly being selectively settable by an axially biased stop.

2. The orthopaedic brace of claim 1, wherein said stop comprises a retaining pin, and said hinge assembly includes a plurality of retaining apertures corresponding to particular ranges of motion and configured to receive said retaining pin.

3. The orthopaedic brace of claim 2, wherein said plurality of retaining apertures are circumferentially space about the axis of rotation.

4. The orthopaedic brace of claim 3, wherein said hinge assembly includes a pair of opposing plates, each plate having a plurality of apertures forming a plurality of opposing pairs of apertures that correspond to said plurality of retaining apertures for receiving said retaining pin.

5. The orthopaedic brace of claim 4, wherein said pair of opposing plates are coupled to one of said first and second plates, and pivotally retain the other one of said first and second plates.

6. The orthopaedic brace of claim 2, wherein said retaining pin is coupled to an axially displaceable and rotatable adjustment knob.

7. The orthopaedic brace of claim 2, wherein said stop is axially biased by a spring assembly.

8. The orthopaedic brace of claim 7, wherein said spring assembly includes a spring retained by an adjustment knob that is rotatable to selectively position said retaining pin axially over one of said plurality of retaining apertures.

9. An orthopaedic brace comprising:

an upper strut;

a lower strut; and

a hinge assembly disposed between said struts and configured to allow movement of one of said struts about an axis corresponding to a joint axis, said hinge assembly settable into any one of a plurality of positions corresponding to a plurality of ranges of motion of said struts about the axis, said hinge assembly having an axially actuated and rotatably mounted adjuster operable to selectively set said hinge assembly.

10. The orthopaedic brace of claim 9, wherein said hinge assembly includes a plurality of retaining apertures corresponding to said plurality of positions, and said adjuster includes a retaining pin configured to selectively engage one of the plurality of retaining apertures to limit the range of motion of said hinge assembly.

11. The orthopaedic brace of claim 10, wherein said plurality of retaining apertures are circumferentially spaced about the axis of rotation.

12. The orthopaedic brace of claim 11, wherein said hinge assembly comprises opposing plates, each plate having a pivot aperture and a plurality of apertures forming a plurality of opposing pairs of apertures that correspond to said plurality of retaining apertures for receiving said retaining pin.

13. The orthopaedic brace of claim 12, wherein said retaining pin is receivable into any one of said plurality of pairs of apertures from a front side of opposing plates and further comprising a second retaining pin that is manually insertable from a back side of said opposing plates, wherein one of said retaining pin and said second retaining pin limits flexion and the other of said retaining pin and said second retaining pin limits extension.

14. The orthopaedic brace of claim 10, wherein said adjuster is axially biased by a spring assembly.

15. The orthopaedic brace of claim 14, wherein said spring assembly includes a spring retained by said adjuster that is rotatable to selectively position said retaining pin axially over one of said plurality of retaining apertures.

16. An orthopaedic brace comprising:

an upper strut;

a lower strut;

a hinge assembly disposed between said struts and configured to allow movement of one of said struts about an axis corresponding to a joint axis, said hinge assembly including opposing plates, each opposing plate containing a pivot aperture and a plurality of circumferential apertures forming pairs of retaining apertures, each pair of retaining apertures corresponding to a range of motion of said struts about the axis, said opposing plates rigidly connected to one of said upper and lower struts and configured to pivotally retain the other strut therebetween; and

an adjustment knob carried on said hinge assembly and including a retaining pin for engagement in a selective one of pairs of retaining apertures to select a range of motion of said struts about the axis.

17. The orthopaedic brace of claim 16, wherein said adjustment knob is axially actuable to select one of said pairs of retaining apertures.

18. The orthopaedic brace of claim 17, wherein said adjustment knob is rotatably mounted to one of said opposing base plates.

19. The orthopaedic brace of claim 17, wherein said adjustment knob comprises:

a bezel rigidly attached to said retaining pin; and

a spring assembly operable to bias against said bezel to maintain said bezel in a locked position wherein said retaining pin is engaged with a selective one of said plurality of apertures, and configured to permit axial actuation of said bezel to disengage said retaining pin from the selective one of said plurality of apertures.

20. The orthopaedic brace of claim 19, wherein said bezel is actuated axially outwardly to disengage said retaining pin.

21. The orthopaedic brace of claim 19, wherein said bezel includes a degree scale corresponding to said pairs of retaining apertures to visually indicate a selected range of motion.

22. An orthopaedic brace comprising:

an upper strut;

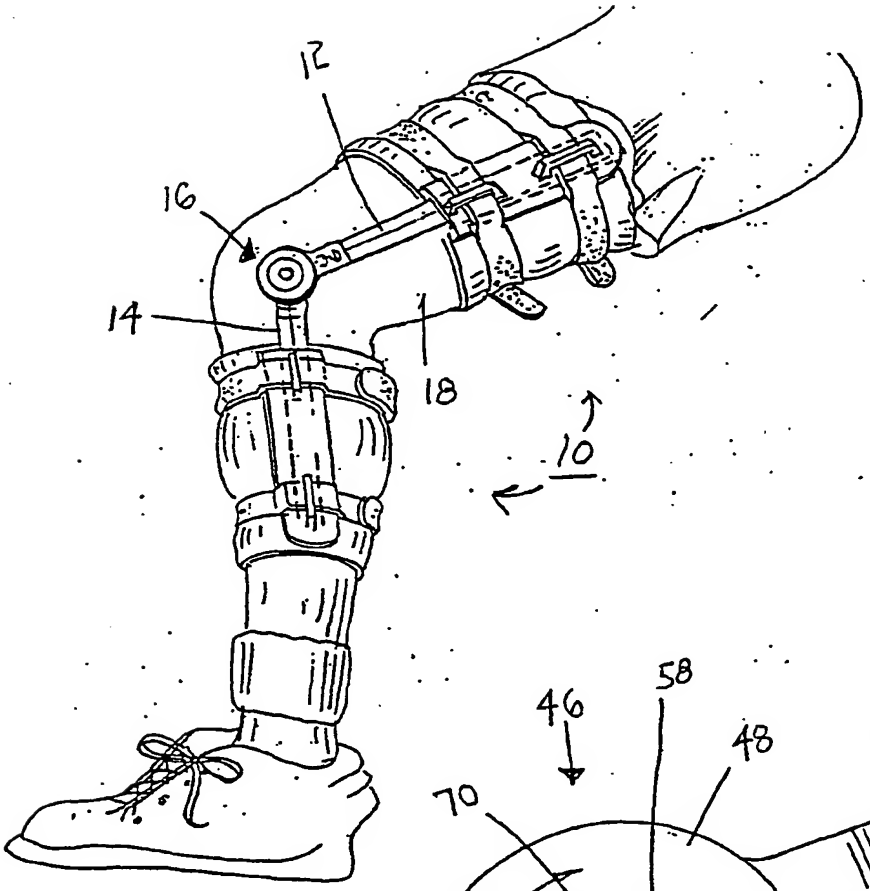
a lower strut;

an axially actuated adjustment assembly having a first rotatable bezel with a first retaining pin fixed thereto, and a second rotatable bezel with a second retaining pin fixed thereto, said first and second rotatable bezels rotatable independently of each other;

a hinge assembly disposed between said upper and lower struts and providing movement of one of said upper and lower struts relative to the other of said upper and lower struts about an axis corresponding to a joint axis of a user, said hinge assembly including opposing plates each having a pivot aperture, a plurality of apertures, and rigidly coupled to one of said upper and lower struts and pivotally retaining the other of said upper and lower struts therebetween, said first and second rotatable bezels rotatably coupled to said hinge assembly; and

wherein said axially actuated adjustment knob is configured to allow said first bezel and said first retaining pin to engage one of said plurality of pairs of apertures to set flexion, and to allow said second bezel and said second retaining pin to engage another one of said plurality of pairs of apertures to set extension.

FIG. 1



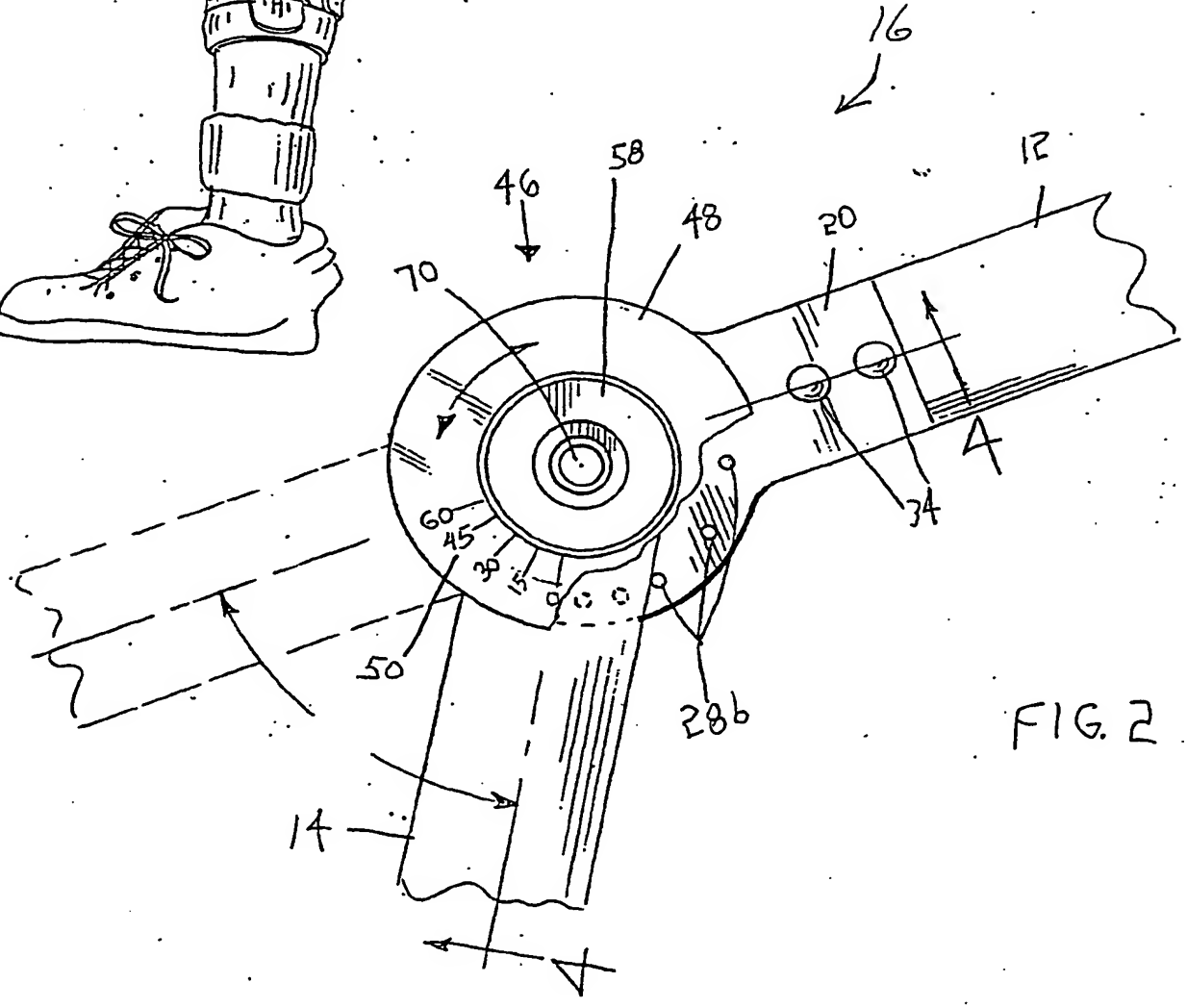


FIG. 2

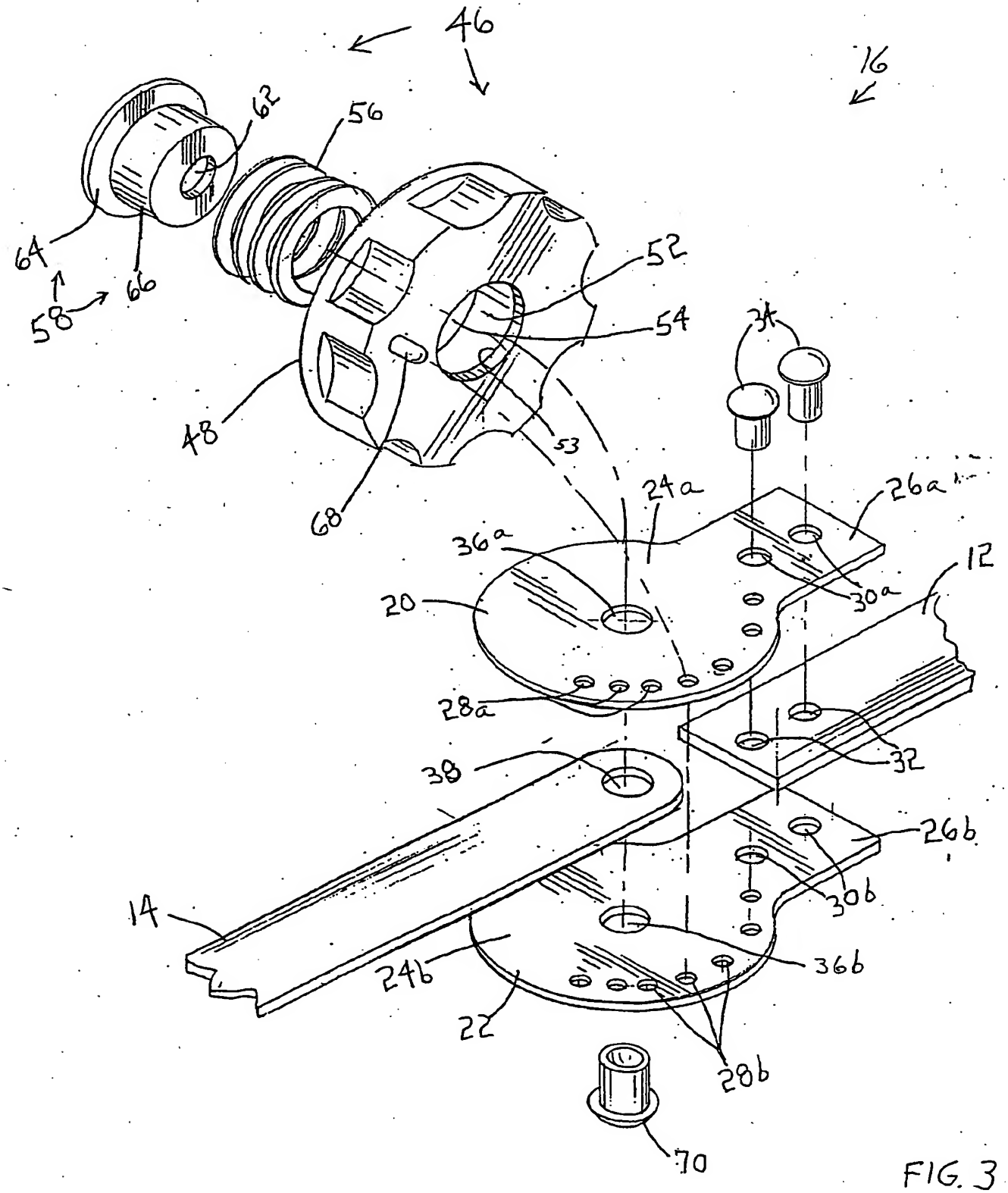

46
16
62
56
64
66
58
52
54
34
48
53
68
24a
26a
36a
12
20
30a
28a
32
38
26b
30b
14
24b
36b
22
28b
70

FIG. 3

FIG. 4A

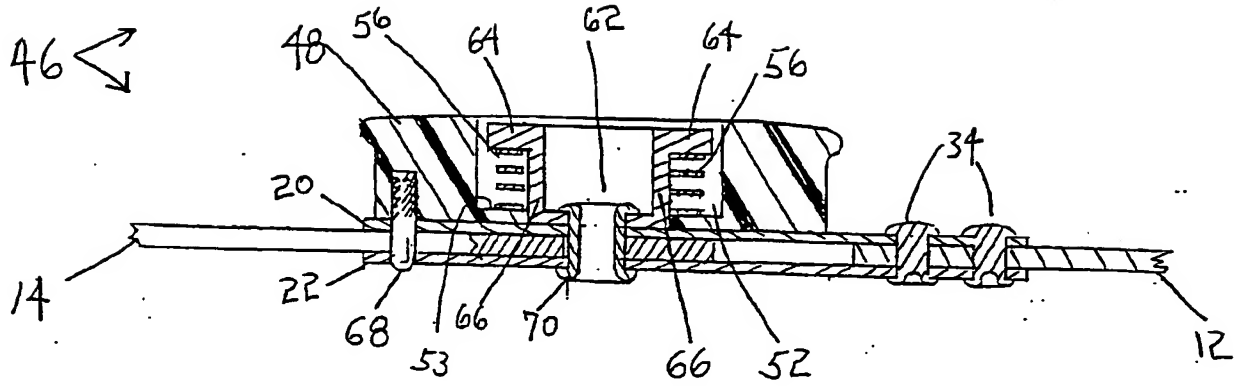
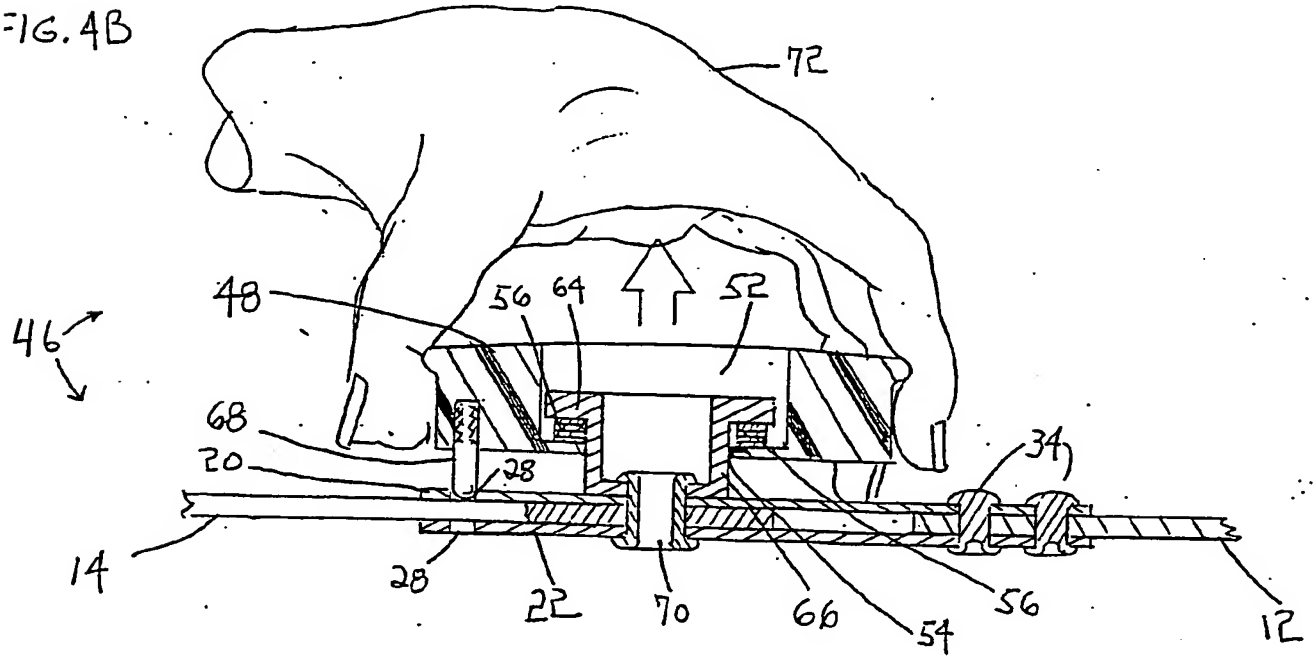

46
48
56
64
62
64
56
34
20
14
22
68
66
70
53
66
52
12

FIG. 4B


72
48
56
64
52
46
68
20
28
34
14
28
22
70
66
54
56
12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/21178

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 5/00
US CL : 602/16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 602/5,16,20,23,26;623/39,43-46

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,433,679 A (MAULDIN) 28 February 1984 (28.02.1984), column 8, lines 1-13.	1-4,6-15
X — A	US 5,885,235 A (OPAHLE) 23 March 1999 (23.03.1999), see Figures 1-3.	1-5,16-18 — 21
X — Y	US 5,292,303 A (BASTYR et al.) 8 March 1994 (08.03.1994), column 6, lines 38-44 and Figures 2-5C.	16-18 — 19-20,22
Y	US 401,933 A (DE CAMP) 23 April 1889 (23.04.1889), page 1, lines 64-71.	19-20,22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
05 September 2001 (05.09.2001)

Date of mailing of the international search report
19 NOV 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703)305-3230

Authorized officer
Mickey Yu/Denise Pothier
Telephone No. (703) 308-1148

Form PCT/ISA/210 (second sheet) (July 1998)